MEMORANDUM OF AGREEMENT FOR THE EXECUTION OF RADIOLOGICAL, NUCLEAR, AND PROCESS SAFETY REGULATION OF TWRS PRIVATIZATION CONTRACTORS

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MEMORANDUM OF AGREEMENT FOR THE EXECUTION OF RADIOLOGICAL, NUCLEAR, AND PROCESS SAFETY REGULATION OF TWRS PRIVATIZATION CONTRACTORS

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Preface

The Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (The Policy) and the Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (The MOA) are companion documents aimed at facilitating and smoothing the implementation of the Tank Waste Remediation System (TWRS) Privatization Program at Hanford.

The foundation of both the Policy and the MOA is that the mission undertaken by TWRS Privatization must be accomplished safely, effectively, and efficiently and that its accomplishment will contribute positively to the overall well-being of the Hanford Site (facilitating the removal and immobilization of the existing large quantities of tank waste). As noted, the Policy and the MOA are intended to facilitate and smooth this accomplishment.

The aim of DOE in proceeding with the radiological, nuclear, and process safety regulation of TWRS Privatization contractors is to establish a regulatory environment that will permit privatization to occur on a timely, predictable, and stable basis with attention to safety consistent with that which would accrue from regulation by an external agency. Also, since external regulation of radiological and nuclear safety at some future date may occur, the exercise of DOE regulation of TWRS Privatization contractors should permit a seamless transition to an external regulatory agency. DOE is patterning its regulation of TWRS Privatization contractors to be consistent with that of the Nuclear Regulatory Commission (NRC).

The Manager of the Richland Operations Office (DOE/RL) has basic responsibility for the safety of activities at the Hanford Site. Due to the special aspects of TWRS Privatization, the Manager of DOE/RL, consistent with the Policy, has chosen to discharge this safety responsibility for TWRS Privatization through a regulatory program described herein rather than through the internal safety management program by which the Manager of DOE/RL ensures the safety of other activities for which the Manager is responsible.

The relationships between DOE and the privatized contractors performing work under fixed-priced contracts are different than the relationships under traditional Management and Operations contracts. For privatization contracts with fixed-prices to be successful, these different safety relationships with the contractors are accompanied by modified relationships among DOE's internal organizations. For example, the arrangement by which the Manager of DOE/RL applies regulation to the TWRS Privatization contractors should be a surrogate for an external regulator (such as the NRC) with strong emphasis on independence, reliability, and openness. At the same time, this regulation must continue to "fit" into DOE's overall internal safety management program.

The Policy is intended to provide a basis for establishing, among DOE Officials and organizations, these modified relationships. The MOA is intended to specify the modified relationships and the associated roles and responsibilities. The MOA cannot be sufficiently detailed to speak to all the interactions among DOE Officials and organizations. The MOA does provide a basis for the key DOE Officials to commit to teamwork in implementing the Policy's objectives, principles, framework, and elements, and in ensuring adequate safety of the TWRS Privatization activities.

It should be specifically noted that the Policy and the MOA cover only the radiological, nuclear, and process safety regulation of TWRS Privatization activities. When "regulation" by DOE is stated, it is this regulation which is intended.

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1.0 Purpose

This Memorandum of Agreement (MOA) is responsive to the *Policy for Radiological*, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (The Policy), which requires that details of interactions among the Manager of the Richland Operations Office (DOE/RL); the Assistant Secretary for Environmental Management (ASEM); and the Assistant Secretary for Environment, Safety and Health (ASEH) for discharge of the responsibilities associated with the Regulatory Program for the regulation of TWRS Privatization contractors be articulated in a MOA. This MOA expresses the interactions among these three key DOE Officials to accomplish the radiological, nuclear, and process safety regulation of the TWRS Privatization contractors, consistent with the Policy. These interactions meet the unique needs of TWRS Privatization and when executed by the three key DOE Officials collectively will fashion the success of this regulation. By signing this MOA, these key DOE Officials commit themselves and their organizations to the interactions, roles, and responsibilities described herein. Particularly, this commitment includes 1) conformance with this MOA in the implementation of the Regulatory Program over the lifetime of the TWRS Privatization Program or until such time as regulation is transferred to an external regulator; 2) allocation by the ASEM of adequate resources and personnel for the initial implementation of the Regulatory Program as described in this MOA; and 3) DOE's best effort in continuing to provide adequate resources and personnel over the lifetime of this Regulatory Program.

As lessons are learned, if modifications to the MOA appear beneficial, these modifications will be incorporated into the MOA. The MOA describes, on a current basis, the regulatory approach. The Manager of DOE/RL is responsible to maintain the MOA accurate and current.

2.0 General Considerations for Interactions

2.1 Teamwork

In this MOA, the significance to the DOE of the success of TWRS Privatization is recognized. This project is the initial significant application of contract reform and regulation of contractors operating privately owned facilities on DOE property to provide fixed-price services to DOE. This MOA provides for teamwork among key DOE Officials and their organizations to achieve radiological, nuclear, and process safety regulation of TWRS Privatization contractors effectively and efficiently. The responsibilities of the individual key DOE Officials and their staffs, in the context of the regulation of TWRS Privatization contractors, are delineated. The teamwork implicit in this MOA provides a basis to achieve success in TWRS Privatization regulation within the overall responsibilities of the key DOE Officials. In the spirit of teamwork, a duty of key DOE Officials and staffs is early identification of interactive situations that may later become issues. These must be promptly elevated to management for resolution, which is to be documented in revisions of this MOA.

2.2 Basic Regulatory Principles

The Policy sets forth five implementing principles of good regulation – independence, openness, efficiency, clarity, and reliability. This MOA addresses these principles as they apply to TWRS Privatization.

2.2.1 <u>Independence</u>

The TWRS Regulatory Official, to whom the Manager of DOE/RL assigns radiological, nuclear, and process safety regulation of TWRS Privatization contractors, shall be independent of all responsibility for the TWRS Program performance. Additionally, the Regulatory Official shall, as a minimum, be organizationally equivalent to and at the same organizational level as the TWRS Program Official to whom the Manager of DOE/RL assigns the performance of the TWRS Privatization Program. The process by which this independence is achieved is described in Enclosure A, which is a part of this MOA.

2.2.2 Openness

The openness principle provides awareness that, in the area of radiological, nuclear, and process safety regulation of TWRS Privatization contractors, the DOE's business is the public's business. The realities for the conduct of this regulation include 1) strict schedules under the Tri-Party Agreement, 2) the need for appropriate protection of proprietary and other controlled information, and 3) the achievement of a significant improvement in the well-being of the Hanford Site through tank waste removal and immobilization. Within these realities, this regulation shall be characterized by openness. The process by which openness will be applied and achieved is described in Enclosure B, which is a part of this MOA.

2.2.3 Efficiency

The efficiency principle for TWRS Privatization regulation means that regulation shall be applied in an even-handed, predictable manner on a timely basis. Foundational to efficiency are:

- a. Clear assignment of responsibilities;
- b. A tailored regulatory process to ensure control of the hazards associated with the activities to be undertaken;
- c. In-so-far as is practicable, a regulatory process that is defined and documented so that expectations on both the contractors and the DOE regulators are clear, understandable, and measurable, and capable of being achieved with necessary quality within the resources and schedules specified;
- d. Objective and timely determination of the sufficiency of actions against defined expectations;
- e. Proactive rather than reactive management leading to:
 - 1. Issues and problems being foreseen or identified early for timely and proper attention to avoid crises rather than react to crises,
 - 2. Contractors being expected to provide continuing, sufficient resources and attention to integrate safety into work planning and performance on a continuing "every day" basis to self-identify and self-correct situations that may lead to problems; and
- f. Sufficient and adequate skills and resources, both for the contractor and DOE, to achieve a continuing condition of safety adequacy; compliance with applicable regulations, rules, and requirements; and conformance to overall safety standards and principles.

2.2.4 Clarity

The regulation of TWRS Privatization contractors shall be coherent, logical, and practicable. Clarity shall be achieved by direct and clear expression of expectations. The regulatory process shall be defined to the level of instructions (procedures and guidance) for performance. The TWRS Regulatory Unit shall develop appropriate procedures and guidance for its own use and the instruction of the contractors. The information shall be made available to the contractors and the public to aid their full understanding of the Regulatory Program. In developing these procedures and guidance, the Regulatory Unit shall adapt proven guidance, procedures, and practices already developed by other entities (such as the NRC) and shall tailor the guidance, procedures, and practices to the specific TWRS Privatization application.

2.2.5 Reliability

The reliability principle for radiological, nuclear, and process safety regulation of TWRS Privatization contractors includes dependability and stability. Dependability, as applied here, means a predictability and lack of variance in regulatory actions by the TWRS Regulatory Official. This shall be achieved through a defined regulatory process, written procedures and guidance for regulatory actions, and appropriately competent personnel. Stability of regulation shall be supported by DOE's best efforts to provide sufficient resources, both personnel and funds, over the lifetime of the Regulatory Program. The process for reliability, particularly emphasizing stability of resources, is described in Enclosure C, which is a part of this MOA.

3.0 Implementation Responsibilities and Authorities

3.1 Manager of DOE/RL

The Policy makes unambiguously clear that the Manager of DOE/RL is responsible and accountable for formulation and execution of the Regulatory Program for the radiological, nuclear, and process safety regulation of TWRS Privatization contractors. This regulatory authority flows from the implementation, by the Manager of DOE/RL, of the basic line manager responsibility for health and safety for all activities under the Manager's purview. This basic health and safety responsibility is equivalent to the Manager's responsibility for DOE/RL program performance. Just as the Manager of DOE/RL assigns program performance to a Program Official on the DOE/RL staff, the Manager of DOE/RL specifically shall assign regulation of TWRS Privatization contractors to a TWRS Regulatory Official on the DOE/RL staff. The assigned regulatory actions performed by the TWRS Regulatory Official shall constitute sanctioned regulatory actions by DOE.

In the discharge of the assigned regulatory execution responsibilities, the TWRS Regulatory Official shall be supported by and shall be head of a specially chartered and dedicated organizational unit (the TWRS Regulatory Unit). This organizational unit is described in Enclosure E, which is a part of this MOA.

The Manager of DOE/RL shall implement TWRS Privatization regulation through the execution of a specified Regulatory Program by the TWRS Regulatory Official. The Regulatory Program, which is the responsibility of the Regulatory Official, consists of all those actions and activities undertaken at DOE/RL that lead to radiological, nuclear, and process safety regulation of the TWRS Privatization contractors. The Regulatory Program shall ensure:

- Conformance with the Policy
- Conformance with this MOA

In the MOA, interactions among the TWRS Regulatory Official and other organizations are described (Enclosure G, Chart 2). The initiative for these interactions resides with the Regulatory Official.

This MOA provides instructions and guidance on expectations of the Regulatory Program. However, should the MOA not cover a matter of importance to the TWRS Regulatory Official, this lack of coverage does not relieve the Regulatory Official from responsibility for the execution of a comprehensive Regulatory Program. If the Regulatory Official desires MOA-level guidance/instructions, it is the Regulatory Official's responsibility to request the guidance/instructions.

Initially, the TWRS Regulatory Official is to develop a Regulatory Plan which gives visibility to the Regulatory Program, describes the activities included in the Program, integrates these activities, and establishes resource needs and schedules. This Plan shall be closely coordinated with the Manager of DOE/RL; organizational units of DOE/RL on which it impacts; ASEM; and ASEH. It is acknowledged that the Regulatory Program will be implemented over time with specific activities needed at specific times during this time period. It is the Regulatory Official's responsibility that each activity of the Regulatory Plan be ready for implementation at the time needed. Assuming proper regulatory performance by the contractors and proper regulatory performance and support throughout the Department, the implementation of the Regulatory Program shall be achieved in a competent and timely manner to support the accomplishment, with adequate safety, of TWRS privatization.

The Regulatory Program includes regulatory activities, infrastructure activities, and management activities.

- Regulatory activities shall focus on interactions with the TWRS Privatization contractors such as 1) reviews of safety submittals, 2) preparation of safety evaluation reports, 3) preparation of authorization agreements, and 4) regulatory oversight. The regulatory activities are described in the documents titled *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors* and *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors* incorporated in Enclosure D, which is a part of this MOA.
- Infrastructure activities shall ensure development of approaches, plans, and procedures to be used by the TWRS Regulatory Official and TWRS Regulatory Unit in the execution of the regulatory function. These include 1) the concept for regulation of TWRS Privatization contractors (Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractor incorporated in Enclosure D), 2) top-level safety standards and principles (Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors incorporated in Enclosure D), 3) process for establishing safety standards and requirements (Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization incorporated in Enclosure D), 4) regulatory process for regulation of TWRS Privatization contractors (DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors incorporated in Enclosure D), 5) guidance documents for the preparation of contractor submittals (e.g. format and content guide for the safety analysis reports), 6) quality assurance procedures to be

used within the Regulatory Unit, 7) administrative procedures (e.g. protection of proprietary information and "docketing") for the operation of the Regulatory Unit, 8) procedures for public information, 9) review plans for the reviews of contractor submittals, and 10) staffing requirements and qualifications.

• Management activities shall ensure 1) development of necessary MOAs, 2) interactions with the NRC, 3) development of the internal organizational structure of the Regulatory Unit, 4) definition of the responsibilities and authorities of positions within the Regulatory Unit, 5) development of resource needs, 6) hiring of competent staff, 7) resource management and reporting, 8) work scheduling, 9) personnel management, and 10) day-to-day management and oversight of the Regulatory Unit.

Chart 2 in Enclosure G of this MOA lists the key activities of the Regulatory Program and indicates the roles and responsibilities of organizations in relation to these activities. The regulatory process and associated regulatory activities are described in the four documents incorporated in Enclosure D, which is a part of this MOA.

- Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005, Revision 0;
- DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003, Revision 0;
- Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, Revision 0; and
- Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004, Revision 0.

3.2 Assistant Secretary for Environmental Management (ASEM)

The ASEM is the Principal Secretarial Officer with line management responsibility for overall TWRS Privatization---both performance and safety. Under this overall responsibility, the ASEM shall ensure that the TWRS Regulatory Program, as with the other programs under ASEM authority, meets the programmatic expectations of the ASEM. This includes such aspects as conformance with Departmental Directives, good fiscal and programmatic management, and effective and efficient performance of the regulatory function. The ASEM assessments, reviews, and reports, through which programmatic performance normally is assured, shall apply to the Regulatory Program. In addition, the ASEM programmatic oversight process shall ensure implementation of the Policy for the lifetime of TWRS Privatization regulation or until such time as this regulation is transferred to an external regulator. ASEM has a key role in the implementation and maintenance of the principle of reliability described in the Policy assuring adequate and stable resources for the Regulatory Program. Enclosure C describes the process for achieving certainty of resources.

3.3 Assistant Secretary for Environment, Safety and Health (ASEH)

The ASEH is the Principal Secretarial Officer who describes the Department's overall policy and approaches to achieve adequate health, safety and environmental protection. As such, the ASEH is the senior internal safety official of the Department. The ASEH 1) provides support in the form of consultation and reviews to the TWRS Regulatory Program to meet the Department's overall policy and approaches and 2) determines, through Independent Oversight, whether the Regulatory Program meets overall Department policy and approaches and,

specifically, the Policy and MOA for the radiological, nuclear, and process safety regulation of TWRS Privatization contractors.

3.3.1 <u>Technical Support</u>

Responsibilities for regulation generally are discharged through the performance of specific regulatory activities. In addition to review and comment on the regulatory activities as they are being formulated for TWRS Privatization by DOE/RL, ASEH technical support will be provided to the TWRS Regulatory Official and the Regulatory Unit in the performance of regulatory activities. Chart 2, Enclosure G, shows the roles and responsibilities of the ASEH technical support function, which are a described part of this MOA. In addition, ASEH technical support may be requested by the Regulatory Official and the Regulatory Unit to participate on teams of technically competent individuals, assembled by planning and negotiation, to support the Regulatory Official and the Regulatory Unit Group Leaders. This technical support is intended to be performed on a dynamic basis with skills applied as work is accomplished, not in post-performance examination of work.

3.3.2 Independent Oversight

The ASEH independent oversight of the TWRS Regulatory Official, including conformance with the Policy and this MOA, is of particular importance for early insight into the efficacy of this approach to contractor regulation under contract reform. Direct interactions with the contractors by ASEH independent oversight shall be coordinated through the Regulatory Official and shall recognize that the TWRS Privatization contractors are fixed-priced contractors providing waste processing service to DOE in contractor-owned facilities, not the more traditional Management and Operations contracts. ASEH independent oversight should apply its oversight approaches to assure that the DOE regulatory approaches under privatization are effective and efficient. Recommendations and corrective actions resulting from ASEH independent oversight shall be directed to the Manager of DOE/RL.

For further details of the roles of the Manager of DOE/RL (and the TWRS Regulatory Official), ASEM, and ASEH, see Chart 2 in Enclosure G, which is attached to this MOA.

Enclosure A

Implementation of the Independence Principle

1.0 Background

An essential feature of the Policy is that DOE/RL's radiological, nuclear, and process safety regulation of TWRS Privatization contractors be achieved with independence, at the regulatory decision level, from the DOE/RL's responsibilities for TWRS Program performance through TWRS Privatization contractors.

2.0 Discussion

2.1 Separation of Responsibilities

The responsibilities for TWRS Program performance and for safety regulation join within the overall DOE/RL organization at the Manager of DOE/RL. Independence of safety regulation, in appearance and fact, shall be established at DOE/RL by strict separation, immediately below the Manager of DOE/RL, of decision making for safety regulation (assigned by the Manager to the TWRS Regulatory Official) from decision making for performance associated with TWRS Privatization (assigned by the Manager to the Assistant Manager for TWRS).

2.2 TWRS Regulatory Official's Authorities

The independent regulatory authority of the TWRS Regulatory Official shall include:

- 1. Authority to approve, and require by inclusion in the contract, the radiological, nuclear, and process safety standards and requirements that must be met by the contractors;
- 2. Authority to authorize specific actions and activities of the contractors with specific prohibition within the contract that these actions and activities cannot proceed until authorized;
- 3. Authority to determine the level of performance of the contractors in meeting safety requirements and commitments through:
 - a. Requiring reports to be filed by the contractors;
 - b. Performing direct inspections, reviews, and observations of the contractors' facilities, actions and activities, including facilities, actions, and activities of contractors' suppliers; and
 - c. Requiring specific actions by the contractors.

(NOTE: Information that may relate to contractor safety performance provided to the TWRS Regulatory Official by the DOE/RL Contracting Officer or the Contracting Officer's staff or as a result of actions taken on account of the Contracting Officer will become part of the public record. The response of the Regulatory Official to such information will be consistent with defined regulatory practices regardless of the source of the information.)

- 4. Authority to require corrective actions by the contractors, including
 - a. Shut down of contractor activities because of safety reasons and
 - b. Communication of regulatory noncompliances to the DOE Enforcement and Investigations staff.

The discharge of activities assigned to the TWRS Regulatory Official may have significant impact on the production/operations performance of the contractors. Yet the Regulatory Official shall make safety decisions from the standpoint of assuring adequate safety independent of the production/operations impacts of the decision. To assure that these decisions are made in a responsible manner:

- 1. The Regulatory Official shall discharge the assigned authorities within a defined and reliable regulatory process;
- 2. With due consideration for proprietary information and other protected information, the basis for the Regulatory Official's decisions shall be open and available to the public; and
- 3. Except for circumstances that cause or threaten imminent danger to the workers and/or the public, the affected contractor shall be provided an opportunity to respond to the Regulatory Official's concerns prior to actions by the Regulatory Official.

(NOTE: From the Regulatory Official's viewpoint, contractors should continuously conform to approved safety requirements and practices so as to avoid regulatory problem situations. This will necessitate continuous and effective integrated safety management by the contractors.)

2.3 Implementation of Independence

The TWRS Regulatory Official shall interact primarily with the contractors and shall keep the TWRS Program Official currently informed. Documentation of interactions between the Program Official and the Regulatory Official, with due regard for proprietary information, shall be made available to the public.

To counter the perception and the potential that the actions of the Regulatory Official might be influenced through control of resources to the Regulatory Official and to support independence and reliability of the Regulatory Program, provision of resources shall be handled according to the process described in Implementation of Reliability Principle, Enclosure C.

The framework for independence is provided through organization and assignment of authorities. The organizational concept supporting independence shall be as shown in Chart 1 of Enclosure G.

The independent functioning of the Regulatory Official relies on strong and correct technical support for Regulatory Official decisions. This technical strength shall come from

- 1. TWRS Regulatory Unit core DOE staff;
- 2. Skilled DOE employees from throughout the DOE complex, and
- 3. Competent support contractors to the Regulatory Unit.

The TWRS Regulatory Unit shall not rely on technical support from the TWRS Program Official nor organizations under the Program Official. However, technical support may be acquired from other elements of DOE/RL and from other organizations within DOE, including the staffs of the ASEM and the ASEH. The TWRS Regulatory Official shall establish a process to document the independence of individuals providing technical support from the Program Official.

Recognizing that independence must be clearly maintained, the TWRS Regulatory Official and the TWRS Regulatory Unit are integral to DOE/RL and shall conform to the internal processes of DOE/RL. Because the Regulatory Unit has many common interests, responsibilities, and capabilities with the DOE/RL Office of Environment, Safety, and Health, this Office shall be viewed by the Regulatory Official as a prime source of regulatory support, when appropriately planned and negotiated. Also, the Regulatory Official shall accommodate assessments by that Office, to inform the Manager of DOE/RL of the performance of the Regulatory Official and the Regulatory Unit.

Consistent with maintaining independence, the TWRS Regulatory Official shall be provided with legal, administrative, and logistics support normally supplied to DOE/RL organization elements by and through DOE/RL.

Additional information on the organizational relationships and interactions of the TWRS Regulatory Official and TWRS Regulatory Unit with other DOE organizations is provided in Enclosure E.

Enclosure B

Implementation of the Openness Principle

1.0 Background

An essential feature of the Policy is that, with consideration for protection of proprietary and other controlled information, regulation of TWRS Privatization contractors be conducted with openness and with access to information by the public.

Openness is intended to enhance public knowledge of the regulatory process and to support completion of regulatory actions in a timely manner. DOE shall not control nor inhibit the release of information to the public. Rather, DOE shall embrace the fundamental premise of openness that all pertinent information, not intentionally withheld because of expressed reasons, be available to the public.

2.0 Discussion

2.1 Responsibility for Openness

The responsibility for the execution of "openness" that flows from the Policy shall be with the TWRS Regulatory Official. This responsibility shall be discharged with close interaction with the DOE/RL Office of External Affairs and with the DOE/RL General Counsel. The Regulatory Official shall ensure that openness activities in support of the Openness Principle are defined and implemented in the spirit of providing information to the public and, of equal importance, obtaining public input. The large majority of openness activities shall be conducted by the Regulatory Official and members of the TWRS Regulatory Unit. Contractor participation, in support of the Regulatory Official's openness activities, shall be limited to participation that is essential or voluntary.

2.2 Openness

Openness under the TWRS Regulatory Official shall include those activities that maximize information availability to the public, provide for public access to that information, and provide opportunity for the public input. Openness shall be conducted with due regard to the safe and timely performance of TWRS Privatization and with due consideration of proprietary interests. Openness activities conducted by the Regulatory Official shall rely on DOE/RL staff functions to inform the Regulatory Official of DOE or DOE/RL directives and practices that influence the implementation of the openness principle.

2.3 Openness Planning

A primary action in conforming to the openness principle shall be to integrate openness into the regulatory process through the development of an Openness Plan that describes and schedules openness activities. The Plan shall recognize that there is wide latitude for achievement of openness. The Plan shall recognize that openness basically serves the TWRS Regulatory Official, and that initiative for openness is the responsibility of the Regulatory Official.

2.4 Openness Activities

The TWRS Regulatory Official shall include, as integral to the regulatory process, openness activities and planning. Activities to be considered shall include

- 1. Instructions and procedures for openness performance;
- 2. Designation and separation of "protected" information from "open" information;
- 3. Establishment of dockets and information files for the orderly management and display of information;
- 4. Programs and schedules for information meetings;
- 5. Definition of the framework for public input to the regulatory process;
- 6. Establishment of schedules for public interactions; and
- 7. Identification of interested groups and individuals.

Enclosure C

Implementation of the Reliability Principle

1.0 Background

An essential feature of the Policy is that radiological, nuclear, and process safety regulation of the TWRS Privatization contractors be reliable---not subject to wide variations in application, performed according to a defined process, not subject to individual preference and whims, and stable over the term of the application of regulation. The application of the reliability principle to the regulation of the TWRS Privatization contractors is of particular importance for effective and efficient regulation.

This Enclosure, which is incorporated into the MOA, provides descriptions of the actions to be taken by DOE to maintain the essential reliability of the regulation of TWRS Privatization contractors.

2.0 Discussion

2.1 Nature of the Regulation of TWRS Privatization Contractors

By Policy, radiological, nuclear, and process safety regulation of TWRS Privatization contractors is to be consistent with external regulation. This provides the basis for seamless transfer of regulation from DOE jurisdiction to an external regulator, should this occur. The TWRS Regulatory Official and the TWRS Regulatory Unit are acting as a surrogate for an external regulator.

2.2 Essential Reliability Actions

In order to provide for reliability of the regulation of TWRS Privatization contractors, three actions are needed.

- 1. Definition of a regulatory process;
- 2. Competent personnel to implement the process; and
- 3. Stability of resources for the formulation and implementation of the process over the full life of this regulation.

2.3 <u>Performance of Essential Reliability Actions</u>

1. Definition of the regulatory process.

The TWRS Regulatory Official, under the authority of the Manager of DOE/RL, is charged with executing safety regulation of TWRS Privatization contractors. The documents of Enclosure D represent a basis for defining the regulatory process to the level of procedures and guidance sufficient for conduct of the regulatory work by the TWRS Regulatory Unit. The same information will provide understanding to the contractors and the public on the nature of the implementation of the regulatory process.

A necessary feature for reliability of the TWRS Regulatory Program is to provide for stability of the baseline regulatory expectations. The stability of baseline regulatory expectations is supported by the Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004 (see Enclosure D to this Memorandum of Agreement). Equally important to the stability of the baseline regulatory expectations is stability in the change to this baseline. The regulatory process shall include a sanctioned change mechanism, under the TWRS Regulatory Official, that is sufficiently defined and deliberate to insulate the process from unwarranted change. The Regulatory Official will invoke the change process to maintain adequate protection. Cost benefit analysis should be used for safety enhancements. Enhancement activities that do not impact the regulatory basis are negotiated between the contractor and the DOE Program Official. Attempted instances at informal regulatory change---without the sanctioning mechanism--are to be reported to the Regulatory Official. The sanctioned change mechanism for adequate protection shall be designed to promptly consider the need for change and the specific applicability of change, to examine the basis and justification for change as applied to the contractor's activities, and to provide for prompt and documented disposition of proposed change.

The Policy requires that the Regulatory Program be consistent with the concepts and principles of NRC regulation. The Regulatory Official shall use applicable NRC practices, which by experience have proven effective. These practices shall be tailored for application to the regulation of TWRS Privatization contractors. In addition, the Regulatory Official shall establish a continuing, defined interactions with the NRC staff, to the extent feasible and acceptable to NRC, that is most beneficial to both agencies.

2. Competent personnel.

The matter of competent personnel is a major and continuing challenge. The TWRS Regulatory Unit needs to have a competent core staff to exercise direct DOE responsibility for the Regulatory Program. The TWRS Regulatory Official, in close cooperation with the DOE/RL Personnel organization, shall give high priority to obtaining and maintaining a competent Regulatory Unit. The goal for having the Regulatory Unit in place is August 1996.

In order to support the core DOE staff in the TWRS Regulatory Unit with additional expertise, the TWRS Regulatory Official shall plan and make arrangements for specific skills from throughout the DOE complex and from selected agencies other than DOE. The selected individuals shall pass an independence review (See Enclosure A). Arrangements and resources for this support shall be established well in advance. The staff of the DOE/RL Office of Environment, Safety, and Health; the staff of the ASEH; and the staff of the ASEM shall be considered as prime sources of skilled experts to support the Regulatory Unit.

As a continuing element of support for reliable regulation, the TWRS Regulatory Official should have under contract an engineering/technical support organization that can assemble a wide array of engineering/technical expertise. Experience in dealing with NRC or NRC licensees should be a key consideration in selecting this regulatory support organization. The regulatory support organization should commit to a continuity of personalities that manage the support to the Regulatory

Official. Continuity is essential in providing the confidence and stability necessary for regulatory success.

For effective and efficient accomplishment of a stable regulatory process, preparation for all regulatory activities shall be scheduled and managed by the TWRS Regulatory Official to assure availability at time of need. A major responsibility of the Regulatory Official shall be to bring the regulatory process to a functioning condition at the time needed.

3. Stability of resources for regulation.

A major uncertainty of multi-year programs can be the erosion, over time, of resources ---personnel and funding---to maintain the program. In order to assure certainty of sufficient continuing resources for the regulation of the TWRS Privatization contractors, the signatories to this MOA commit to the following process.

- a. Resources (personnel and funds) shall be provided by the ASEM as part of the overall budget for the TWRS Privatization Program. The budget for the TWRS Regulatory Program shall be a separate line item specifically authorized by the ASEM.
- b. The TWRS Regulatory Official, based on a regulatory budget plan, shall identify and justify the budget for the Regulatory Program. This budget shall be recommended by the Regulatory Official to the Manager of DOE/RL. Concurrent with the recommendation to the Manager of DOE/RL, copies of the recommended budget shall be supplied by the Manager of DOE/RL directly to the ASEM and the ASEH.
- c. The recommended Regulatory Program budget shall be requested by the Manager of DOE/RL, as a separate line item in the overall budget for the TWRS Privatization Program. The ASEH shall concur on this request.
- d. The requested Regulatory Program budget shall be approved and allocated by the ASEM. If the ASEM approved budget varies from the DOE/RL requested budget by more than ten percent, a justification for the variance shall be placed in the public records of the Regulatory Program. The ASEH shall concur on the ASEM allocation.
- e. Changes to the budget allocation for the Regulatory Program shall be made only by recommendation of the Manager of DOE/RL with concurrence of the ASEM and the ASEH. The Regulatory Official shall develop an impact analysis of the change. The change and the impact analysis shall be placed in the public records of the Regulatory Program.

Enclosure D

Descriptions of the Elements of the TWRS Privatization Regulatory Process

This Enclosure, which is incorporated into the MOA, includes four documents that provide information on and the framework for the interactions between the TWRS Regulatory Official (and the TWRS Regulatory Unit) and the TWRS Privatization contractors. These documents provide descriptions of the regulatory activities of the TWRS Regulatory Program in sufficient detail for implementation by the Regulatory Unit and for understanding by the contractors and the public of the nature of the regulatory process.

The four documents, which constitute this Enclosure are:

- Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005, Revision 0;
- DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003, Revision 0;
- Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, Revision 0; and
- Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004, Revision 0.

Enclosure E

DOE/RL Organization for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors

1.0 Background

The Policy is achieved principally by implementation of a defined regulatory process by a dedicated Regulatory Unit under the direction of a TWRS Regulatory Official. The effectiveness and efficiency of the Regulatory Unit is highly dependent on its interactions with other organizational elements of DOE. This enclosure defines the interactions among the DOE organizations that shall have responsibilities associated with the implementation of the Policy.

2.0 Discussion

2.1 <u>Basis for DOE/RL Regulation</u>

In implementing the Policy, the responsibility for the radiological, nuclear, and process safety regulation of TWRS Privatization contractors is explicitly recognized as residing with the Manager of DOE/RL under the Manager's general line responsibility for the safety of those activities under the Manager's purview.

The Nuclear Regulatory Commission (NRC) has articulated five principles of good regulation, which have been incorporated into the Policy as applicable to DOE's regulation of TWRS Privatization contractors. These principles---independence, openness, efficiency, clarity, and reliability support the decision to assign the regulation of TWRS Privatization contractors to a separate and independent DOE/RL official whose only assignment is this regulation.

2.2 <u>Interactions with TWRS Program Official</u>

The independence associated with the organizational approach defined in Enclosure A clearly insulates the TWRS Regulatory Official from production/operations matters, which the Manager of DOE/RL has separately assigned to the Assistant Manager for TWRS (TWRS Program Official). The Regulatory Official shall be focused entirely on the regulation of TWRS Privatization contractors and shall keep the Program Official informed, on a current basis, of regulatory matters. Additionally, the Regulatory Official shall keep the Program Official informed of regulatory schedule matters, anticipated schedule modification issues, and special needs. Independence shall be achieved by an "arms-length" relationship between the Regulatory Official and the Program Official. Documentation of interactions between the Regulatory Official and the Program Official shall be available to the public.

2.3 Interactions with DOE/RL Internal Safety Official

The DOE/RL Internal Safety Official (currently the Director, Office of Environment, Safety and Health, DOE/RL) exercises assigned responsibilities within DOE/RL as follows:

- 1. Overall DOE/RL environment, health, and safety policy;
- 2. Guidance and assistance in the understanding and implementation of that policy throughout DOE/RL; and

3. Oversight of performance against DOE/RL policy and requirements.

These responsibilities shall be exercised with respect to the TWRS Regulatory Unit as an organizational element within DOE/RL. However, details concerning the interaction of the DOE/RL Internal Safety Official directly with the TWRS Privatization contractors shall be agreed upon between the Regulatory Official and the Internal Safety Official, since these contractors are performing fixed-price work, a significant departure from the traditional contracting approach.

Because of the similarity of skills needed by the DOE/RL Internal Safety Official and the TWRS Regulatory Official, the two organizations shall consider, with due consideration for independence, resources, and schedules, providing skill assistance to each other. These opportunities shall be determined on a specific basis.

In discharging responsibility for assessment of performance, the DOE/RL Internal Safety Official may identify particular TWRS Regulatory Official activities in which the Internal Safety Official may have a particular interest. Arrangements, on a specific basis, shall be made to assure access to these Regulatory Official activities.

2.4 Interactions with Other DOE/RL Officials

With due regard for independence (Enclosure A) and reliability of resources (Enclosure C), the TWRS Regulatory Official shall have freedom to interact with DOE/RL Officials other than the TWRS Program Official and the DOE/RL Internal Safety Official (noted above) consistent with the practices of DOE/RL.

2.5 Interactions with ASEM and ASEH

It is anticipated that the staffs of the ASEM and the ASEH will have particular interest in the performance of the TWRS Regulatory Official and in the implementation of the Policy and the MOA. Of specific interest will be interactions during the development and implementation of the regulatory process. The Regulatory Official will consult with the Office of Environment, Safety, and Health (Deputy Assistant Secretary for Nuclear facility Safety) on a quarterly basis. The Regulatory Official will solicit and disposition recommendations on safety and regulatory matters. Chart 2 of Enclosure G of this MOA describes the roles and responsibilities.

3.0 Initial DOE/RL Organization for Regulation

Consistent with the Policy, the MOA, and the organizational concepts discussed in this Enclosure, an Initial DOE/RL Organization for the regulation of TWRS Privatization contractors is identified in Chart 3 of Enclosure G. This TWRS Regulatory Unit is headed by the TWRS Regulatory Official (Director) and reports directly to the Manager of DOE/RL. This initial organization meets the organizational requirement associated with the principle of independence (Enclosure A and Chart 1 of Enclosure G).

Enclosure F

Initial DOE/RL Organization for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors

1.0 Regulatory Unit

This organizational unit (referred to elsewhere as the TWRS Regulatory Unit) performs the radiological, nuclear, and process safety regulation of the TWRS Privatization contractors. Organizationally, this Office consists of the Director (who is the TWRS Regulatory Official), three Regulatory Groups, and the Senior Technical Team. These four organizational sub-units all report directly to the Office Director.

1.1 Regulatory Unit Groups

Each of the three groups is headed by a Group Leader. Each group consists of core DOE technical staff sufficient to assemble and manage the competent skills---from within the DOE/RL staff, from other DOE organizations in the DOE complex, and from sources outside DOE---to accomplish the group's assigned mission. The group's core DOE staff is technically competent, small in number, and accomplishes its mission through teams assembled for task performance. The core staff defines work and necessary resources; maintains regulatory schedules; and assures that regulatory performance is timely, is documented, and is thoroughly accomplished by assembled technically competent individuals. The core staff speaks for DOE/RL regulation of TWRS Privatization contractors in its assigned area.

1. Standards and Requirements Group

- a. Reviews the sets of safety standards recommended by the contractors and, if satisfied, recommends to the Director approval of the sets of safety standards that, when properly implemented, should conform to top-level radiological, nuclear, and process safety standards and principles, comply with applicable laws and regulations, and provide adequate safety;
- b. Ensure a process is in place to identify standards needs, identify sources of existing standards, initiate development of additional standards where needed;
- c. Implements a "backfit" process for standards implementation in a timely manner for standards not included in the initial set; and
- d. Interacts with other groups on standards.

2. Activities Authorization Group

- a. Defines the criteria for review and approval of contractors' authorization requests for construction, operations, and deactivation;
- b. Manages the assembly of competent skills to provide a basis for approval of authorization requests to construct, to operate, and to decontaminate;

- c. Performs reviews of contractors' authorization requests and prepares safety evaluation reports;
- d. Provides a point-of-contact for external oversight of the authorization actions that are a part of the regulation of TWRS Privatization contractors;
- e. Maintains the documented record of the TWRS Regulatory Program and interacts with the public to obtain public input.

3. Verification and Confirmation Group

- a. Approves the contractor's Integrated Safety Management Plan;
- b. Approves the contractors QA plan implementation;
- c. Determines that the contractors have compliance management processes for identification and correction of non-compliance;
- d. Remains knowledgeable of the contractors' in-plant conditions relative to radiological, nuclear, and process safety and any changes thereto;
- e. Inspects the contractors' activities;
- f. Investigates off-normal situations;
- g. Provides a point-of-contact for external oversight of the regulation of TWRS Privatization contractors;
- h. Maintains the documented record of the TWRS Regulatory Program and interacts with the public to obtain public input; and
- i. Initiates corrective actions, initiates enforcement action under the contract, or communicates noncompliances to nuclear safety requirements to DOE's 10 CFR 820 enforcement organization.

1.2. Senior Technical Team

- 1. Special team with senior technical experts to review, analyze and resolve technical safety matters.
- 2. Director has wide latitude in application of the STT:
 - a. Senior technical personnel to support actions, as needed, under the Director;
 - b. Performance and review of technical activities under the Director; and
 - c. Recommend actions by the Director on technical matters.
- 3. Senior technical personnel are assembled, as needed, from sources such as DOE/RL organizations, DOE Headquarters organizations, and consultants, to accomplish work assigned by the Director.

2.0 Senior Expert Review (SER)

Three mature individuals, highly experienced in safety and regulation, are individually available to the Manager of DOE/RL, and provide the Manager with:

- 1. Senior views of the radiological, nuclear, and process safety regulation of TWRS Privatization contractors;
- 2. Views, on a selected basis, of the actions of the TWRS Regulatory Official on particular regulatory responsibilities and issues; and
- 3. Views on resolution of disputed regulatory issues.

Enclosure G

Charts of Roles, Responsibilities and Organization

Chart 1 Organization Concept---Independence Principle

General Overview

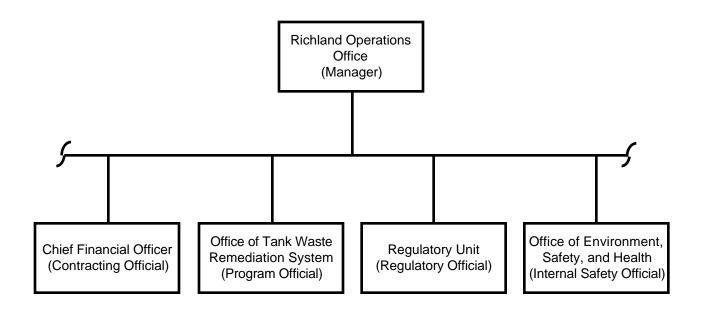


Chart 2
Roles and Responsibilities

REGULATORY ACTIVITIES				
	ACTIVITY	ROLES	RESPONSI- BILITIES	VEHICLES
1.	Review & approve contractors' integrated safety manag't plans	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	 Contractor submits ISMP and associated information DOE/RL evaluation doc't
2.	Review & approve contractors' recommended standards	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	Contractor submits SRD and associated information DOE/RL evaluation doc't
3.	Initial safety reviews	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	Contractor submits ISAR and associated information DOE/RL evaluation doc't
4.	Construction authorization reviews	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	 Contractor submits PSAR and associated information DOE/RL evaluation doc't DOE/RL authorization agreement
5.	Operating authorization reviews	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	 Contractor submits FSAR and associated information DOE/RL evaluation doc't DOE/RL authorization agreement
6.	Deactivation authorization reviews	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	Contractor submits DSA and associated information DOE/RL evaluation doc't DOE/RL authorization agreement
7.	Regulatory oversight of contractors	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	Contractor submits annual reports & associated info DOE/RL evaluation doc't

ISMP	Integrated Safety Management Plan
SRD	Safety Requirements Document
ISAR	Initial Safety Analysis Report
PSAR	Preliminary Safety Analysis Report
FSAR	Final Safety Analysis Report
DSA	Deactivation Safety Assessment

Chart 2 (continued)

Roles and Responsibilities

INFRASTRUCTURE ACTIVITIES					
ACTIVITY	ROLES	RESPONSI- BILITIES	VEHICLES		
Concept for radiological, nuclear and process safety regulation	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
2. Top-level safety standards and principles	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
3. Standards process	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
4. Regulatory process description	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
5. Format & content guide for safet standards & requirements	• EM - R • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
6. Format & content guide for integrated safety management plan	• RL - D • EM - R • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
7. Format & content guide for safet analysis reports	• RL - D • EM - R • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
8. QA program for Regulatory Unit	• RL - D • EM - R • EH - R	• RL - I • EM - C • EH - C	DOE/RL document		
9. Administrative procedures for Regulatory Unit operation	• RL - D • EH - R	• RL - I • EH - C	DOE/RL document		
10. Administrative procedures for Regulatory Unit public input	• RL - D • EH - R	• RL - I • EH - C	DOE/RL document		
11. Review plans for contractor submittals	• RL - D • EM - P • EH - P	• RL - I • EM - C • EH - C	DOE/RL document		
12. Staffing requirements and qualifications	• RL - D • EM - R • EH - R	• RL - I • EM - C • EH - C	DOE/RL document		

Chart 2 (continued)

Roles and Responsibilities

MANAGEMENT ACTIVITIES					
	ACTIVITY	ROLES	RESPONSI- BILITIES	VEHICLES	
1. Regul	atory Policy	• RL - D • EH - P • EM - P	• RL- I • EM - A • EH - A	DOE/RL document	
2. DOE I	MOA	• RL - D • EH - P • EM - P	• RL- I • EM - A • EH - A	DOE/RL document	
3. NRC	MOA	• RL - D • EH - P • EM - P	• RL- I • EM - A • EH - A	DOE/RL document	
4. Regula	atory Unit organizational are	• RL - D	• RL - I • EH - C • EM - C	DOE/RL document	
tions, author		• RL - D	• RL - I • EH - C • EM - C	DOE/RL document	
	atory Unit resource ements	• RL - D • EM - R • EH - R	• RL - I • EH - A • EM - A	DOE/RL document	
	atory Unit resource gement & reporting	• RL - D	• RL - I	DOE/RL document	
8. Regul	atory Unit staffing	• RL - D	• RL - I • EH - C • EM - C	DOE/RL document	
9. Regul	atory Unit work schedule	• RL - D	• RL - I	DOE/RL document	
10. Regul	atory Unit management	• RL - D	• RL - I	Not Applicable	
11. Regula	atory Unit independent ght	• EH - D • RL - P	• EH - I • RL - P	EH oversight report	
12. Regulario oversi	atory Unit programmatic ght	• EM - D • RL - P	• EM - I • RL - P	EM review report	

Chart 2 (continued)

Roles and Responsibilities

NOTES

Key Organizations 1. DOE Richland Operations Office (RL)

2. DOE Environmental Management (EM)

3. DOE Environment, Health, and Safety (EH)

Roles Degree of participation the key organization contributes to the regulatory activity:

1. Develop (D) - Formulate the regulatory activity by in-house skills or assembly of skills

2. Participate (P) - Contribute skills in development

3. Review (R) - Examine the development (does not include independent oversight)

Responsibilities Degree of accountability of the key organization for the regulatory activity:

1. Issue (I)
 - Accountable to formulate and implement as effective the regulatory activity

Assure necessary approvals are obtained

- Respond appropriately to comments

- Issuance is shown by signature and date

2. Approve (A)

- Accountable to agree with issuance

- Issuance cannot be effective without agreement

- Agreement is indicated by concurrence signature and date

3. Comment (C)

- Accountable to provide views in areas of expertise or organizational responsibility

- Issuance can be effective without comments

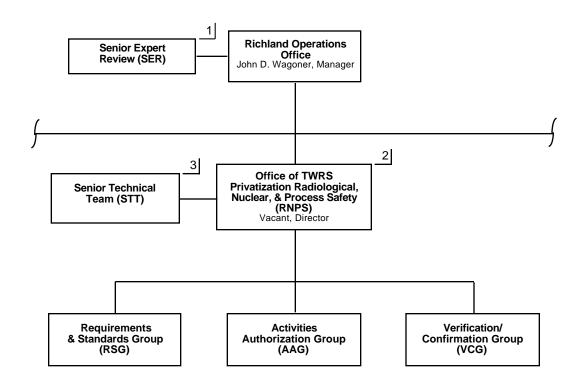
NOTE: Elements of the Regulatory Program include submittals from the contractors. The roles and

responsibilities designations refer to the DOE actions associated with the contractor submittals.

Chart 3a

Initial DOE/RL Organization for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors

General Organizational Structure



The Senior Expert Review (SER), provided individually by three senior radiological, nuclear, and process safety and regulatory experts, is not an element of the RNPS. Each individual provides views directly to the RL Manager.

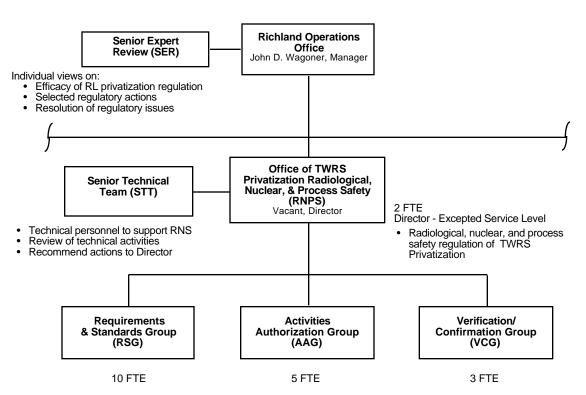
The RNPS consists of the RSG, AAG, and VCG. The RNPS performs exclusively the regulation for radiological, nuclear, and process safety of the Tank Waste Remediation System Privatization.

The STT is a special team that is assembled as required for expertise needed in the analysis, review, resolution and recommendations with respect to technical issues and documents.

Chart 3b

Initial DOE/RL Organization for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors

Resource Requirements and Responsibilities



- Review and Approval of Standards and Requirements
 - Training and Qualifications
 - Radiation Exposure Standards for Workers / Accident conditions
 - Occurance Reporting Technical Standards for
 - Processing Plant
- Process Safety Management
- Preparation of Documentation for Regulatory Process
 - Administrative Framework
 - Format & Content Guides
 - Standard Review Plans
 - Application Requirements

- Review of Safety Analysis Reports Review of Integrated Safety Management Plan
- Managernen Fian
 Review of Hazard Analysis
 Review and Approval of Quality
 Assurance Plan
 Review of Documentation for
- - Regulatory Process
 Authorization Basis for Construction
 - Authorization Basis for Operations
- Authorization Agreement
- Authorization Basis for Deactivation

- Audit of Quality Assurance Plan and Activities
- Review of Occurence Reporting
- Preparation of Documentation for Regulatory Process
 - Inspection & Enforcement
- Authorization Amendments
- **USQ** Reviews